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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/989,130      | 11/21/2001  | Richard W. Titball   | 3974-3              | 1328             |

7590 01/27/2003  
NIXON & VANDERHYE P.C.  
8th Floor  
1100 North Glebe Road  
Arlington, VA 22201-4714

|                |              |
|----------------|--------------|
| EXAMINER       |              |
| CHEN, SHIN LIN |              |
| ART UNIT       | PAPER NUMBER |

1632

DATE MAILED: 01/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/989,130

Applicant(s)

Titball et al.

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 21, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 32-38 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 32-38 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 32-38, drawn to a pharmaceutical composition comprising an antibody conjugated to a lipase or a lipase component and/or a pharmaceutical composition comprising a pharmaceutical agent that is a **nucleic acid**, such as polynucleotide, protected in a liposome, and a pharmaceutical package comprising said composition, classified in class 536, subclass 23.1.
  - II. Claims 32-38, drawn to a pharmaceutical composition comprising an antibody conjugated to a lipase or a lipase component and/or a pharmaceutical composition comprising a pharmaceutical agent that is a **protein**, such as an enzyme or hormone, protected in a liposome, and a pharmaceutical package comprising said composition, classified in class 530, subclass 350.
  - III. Claims 32-38, drawn to a pharmaceutical composition comprising an antibody conjugated to a lipase or a lipase component and/or a pharmaceutical composition comprising a pharmaceutical agent that is an **antibody**, protected in a liposome, and a pharmaceutical package comprising said composition, classified in class 424, subclass 130.1.
  - IV. Claims 32-38, drawn to a pharmaceutical composition comprising an antibody conjugated to a lipase or a lipase component and/or a pharmaceutical composition comprising a pharmaceutical agent that is a synthetic **oligonucleotide**, protected

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in a liposome, and a pharmaceutical package comprising said composition, classified in class 536, subclass 24.33.

- V. Claims 32-38, drawn to a pharmaceutical composition comprising an antibody conjugated to a lipase or a lipase component and/or a pharmaceutical composition comprising a pharmaceutical agent that is an **organic compound** other than nucleic acid, antibody, protein and oligonucleotide, such as cancer chemotherapeutic drugs and antimicrobial drugs, protected in a liposome, and a pharmaceutical package comprising said composition, classified in class 514, subclass 1.

Claims 32-38 link(s) inventions I-V. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 32-38. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also M.E.P., § 804.01.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I-V are distinct because they are drawn to compositions having different chemical structures, physical properties and biological functions, and requiring separate search: nucleic

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acids, proteins, antibodies, oligonucleotides, and organic compounds. Search for nucleic acid does not require search for protein, antibody, oligonucleotide or organic compound, and search for protein does not require search for antibody, nucleic acid, oligonucleotide, or organic compound etc. Nucleic acid (polynucleotide) is distinct from oligonucleotide because they have different chemical structures, biological functions and different usages. They have different classifications and require separate search. They are not obvious variants and deemed patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CAR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CAR 1.48(b) and by the fee required under 37 CAR 1.17(I).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

A handwritten signature in black ink, appearing to read 'Shin-Lin Chen' in a cursive style.